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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/543,156	04/20/2006	Tetsushi Taguchi	052075	2620
38834 7590 04/25/2008 WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP 1250 CONNECTICUT AVENUE, NW SUITE 700 WASHINGTON, DC 20036				
EXAMINER				
HA, JULIE				
ART UNIT		PAPER NUMBER		
1654				
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04/25/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/543,156

Applicant(s)

TAGUCHI ET AL

Examiner

JULIE HA

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-6 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF 298)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.
2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Different biodegradable polymer: collagen, atelocollagen, alkali-solubilized collagen, gelatin, keratin, albumin, globulin, fibrinogen, glycosaminoglycan, chitin, chitosan, polyamino acid or polyalcohol;

Different organic solvent: DMSO, DMF, lactic acid, lactic acid oligomer, polyethylene glycol or polypropylene glycol;

Different hardening component: low molecular weight derivative of di or tri-carboxylic acid of the citric acid cycle;

Different electron-withdrawing group: succinimidyl, sulfosuccinimidyl, maleimidyl, phthalimidyl, imidazolyl, nitrophenyl, or tresyl;

Different bonding between different types of tissues (genera): soft and soft, soft and hard, or hard and hard;

Different intravascular material: hemostatic, blood-vessel embolizing, a sealant, or an aneurysm closing material.

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3. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.
4. Applicant is required to elect a single disclosed species of biodegradable polymer, organic solvent, a hardening component (what is in the hardening component), electron-withdrawing (accepting) group, bonding between the types of tissues, and an intravascular material.
5. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).
6. The claims are deemed to correspond to the species listed above in the following manner:

Claims 2-4.

The following claim(s) are generic: Claims 1 and 5-6.

7. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The biodegradable polymers are patentably independent and distinct due to their different structures. For example, collagen (GenBank Accession No. CAA35955) has 316 amino acid residues and globulin (GenBank Accession No. AAR95703) has 229 amino acid residues. Further, search for one would not necessarily lead to the other. Different organic solvent are patentably independent and distinct due to their different structure and their different chemical and physical characteristics. For example, DMSO has the structure

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and has a melting point of 18.5°C; DMF has the structure and has a melting point of -38°C. Further, search for one would not necessarily lead to the other. Different electron-attracting groups are patentably independent and distinct due to their different structures. For example, phthalimidyl group has the structure



and imidazole has the structure . Further, search for one would not necessarily lead to the other. A hardening component consisting of a low-molecular weight derivative are patentably independent and distinct due to their different structures having different modified carboxyl group of a di or tri-carboxylic acid. Further, search for one would not necessarily lead to the other. Different types of tissues are patentable independent and distinct due to the different types of tissues involved in the bonding. For example, a soft tissue includes muscles, tendons, ligaments, nerves, fibrous tissues, blood vessels, fats, etc, while a hard tissue includes bone and cartilage. For example, a search for muscle bonded to blood vessels would not lead to a bone bonded to cartilage, requiring independent searches. Different intravascular material are patentably independent and distinct due to their different structures. For example, a sealant could be composed of biodegradable polymers, while a closing material may be something like a clamp. Further, search for one would not necessarily lead to the other.

8. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

9. The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the

requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

10. **Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.**

11. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. H./

Examiner, Art Unit 1654

/Anish Gupta/

Primary Examiner, Art Unit 1654